FORM NO. 1: APPLICATION FORM FOR ETHICAL CLEARANCE

For Official use only

Application No:	Date Received:	
Name, date and signature of the BMC/CUHAS E&R Committee Member receiving the application	Name:	
	Signature:	
	Date:	

Instructions: All applications for ethics approval should be submitted using this form. The Principal Investigator is required to ensure the information provided is accurate and will sign on this form to indicate that he/she approves the content. The information provided in this form is expected to be complete and adequate for reviewers to make a decision on the final disposition of the proposal.
The Application Form must be TYPED. **Handwritten forms are not acceptable**. Responses should be typed in the blank space/field after each question. All forms to be handed in must be completed in full and relevant signatures must be provided. Should this not be done, the evaluation process will not commence. The forms shall be handed over to the Ethics& Review Secretariat with one copy of the full proposal and the receipt for the payment of the clearance fee.

Title of Proposal/Project			
Name of the Principal Investigator (PI)			
Nationality of the PI			
Current qualifications of PI			
Position/Academic title			
Institution/Department/Unit			
Signature of the PI			
If Research student: Name, signature and approval of Supervisor (include approval letter)	Name:	Signature:	
Contact details for correspondence (include the name of contact if different from the PI)	Physical: Postal: Tel/Mobile: Email:		
All co-investigators (local and foreign)	Name 1. 2. Etc.	Qualifications	Institution/Department
Collaborating Institution(s) and contact person	1. 2. Etc.		
Purpose of Research *(Check **X** in the relevant boxes - double click on check box)*	**Not for degree purposes** ☐ **Postgraduate: degree/diploma (state which)** ☐ Name of degree/diploma:		
Details of the proposed Research			
Starting and ending dates			
Research site in Tanzania			

Research site outside Tanzania (if any)	
Budget (Tsh or $)	
Source of funds/sponsor	
Nature of Research *(Check **X** in the relevant boxes - double click on check box)*	Retrospective study ☐ Prospective study ☐ Longitudinal study ☐ Cross-sectional study ☐ Audit ☐ Review of records ☐ Behavioural study ☐ Anthropological or sociological study ☐ Development and/or Testing of education material/methods ☐ Observational study ☐ Quantitative methods to be used ☐ Qualitative methods to be used ☐ Mixed methods to be used ☐ Other (describe) ☐
Describe further if necessary	

Will this study involve the taking of blood and/or any other biological samples?: Yes ☐ No ☐ NA ☐
Will this study involve shipment of biological samples outside Tanzania?: Yes ☐ No ☐ NA ☐ If Yes, Please attach Material Transfer Agreement
Will this study going to involve data sharing/transfer outside Tanzania?: Yes ☐ No ☐ NA ☐ If Yes, Please attach Data sharing/transfer agreement
Is this an externally sponsored research?: Yes ☐ No ☐ NA ☐ If Yes, Please attach ethics approval letter from foreign ethics committee
Have you applied for ethics approval from the NIMR National Ethics Committee? Yes ☐ No ☐ NA ☐ Please attach if applicable.
Provide the scientific background, study design and objectives and hypotheses. Max 300 words
State the intended value of the project or rationale. Why is it important to conduct this study in Tanzania? Provide relevant references as appropriate. Max. 200 words
State the total duration of the project, and where it will be undertaken in Tanzania (and also in other countries if appropriate)
Provide evidence (such as commitment/endorsement letter) to show that local government officials in the region(s)/district(s) where the proposed research will be conducted have been informed about this study. IF THIS HAS NOT BEEN DONE, describe how you plan to achieve this BEFORE the study starts

Specify the number of the study participants, with scientific justification for sample size, age, gender
Specify recruitment methods, inclusion and exclusion criteria and study end points
Specify data collection procedures, including interviews and sample collection, involving human participants with brief details of actual methods. Attach copies of questionnaires and other data collection tools in English and Kiswahili (If applicable) 400 words
If applicable, describe procedures to be used to process, store and test biological samples (e.g. blood, genital swabs, urine, etc.)
If samples will be taken overseas, are there samples which will be left in Tanzania? Describe procedures to be used in their shipping, storage and when they will be destroyed. Indicate which institution or laboratory samples will be analyzed. Please note that before samples are shipped out of Tanzania, a MTA clearance is required.
Is the technology required for analysis of samples available in Tanzania? Yes ☐ No ☐ NA ☐ If YES, please describe why are samples being taken outside the country
Would local scientist(s) be involved in sample analysis? Yes ☐ No ☐ NA ☐ If YES describe her/his involvement, and if NOT please explain what are the strategies for technology transfer
Specify data management procedures and methods to be used during data analysis
If data will be taken overseas, please describe why are being taken outside the country. Please note that before data are taken out of Tanzania, a DSA is required.
Describe the potential risks, discomfort, distress or hazards that research participants may be exposed to (these may be physical, biological and/or psychological). What precautions will be taken to reduce risks and ensure participants' safety?
Describe potential benefits for the participants and the population where they come from. Are there direct benefits for the people of Tanzania and/or other countries?
Specify how confidentiality of the study participants and data collected will be maintained.

Requirements for Participant Information Sheet *(Check **X** in the relevant boxes - double click on check box)*	
Participant information leaflet is attached. (For written and verbal consent)	Yes ☐ No ☐
Informed Consent Form is attached. (For written consent)	Yes ☐ No ☐
Describe steps to be taken to minimise coercion/undue influence during the consent process	
Describe how you are going to assess the comprehension of the information provided during the consent process	

- Consent will be only verbal ☐
- Consent will be only written ☐
- Consent will be written or verbal (depending on participant's literacy) ☐
- Informed consent is not necessary ☐

State why not:
Request waiver for consent due to the nature of study ☐
Please state why :
If a Questionnaire or Interview is to be used in the research, it must be attached. Is it attached? *If not, the application cannot be considered*. Yes ☐ No ☐
Assent / Guardian form must be attached. Age range of patients/participants/controls: If under 18 years, from whom will consent be obtained?
Please state any other thing that you think could be useful in the evaluation process

Please submit the completed protocol to :	**The Secretariat** CUHAS/BMC Joint Ethics & Review Committee Telephone: +255 28 2500881 Fax: +255 28 2502678